

Practitioner's Docket No. 04132**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of _____
Inventor(s)for _____
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: James C. Willey et al.

Application No.: 010,508,932 Group No.:

Filed: September 24, 2004 Examiner:

For:

METHOD AND COMPOSITIONS FOR THE ASSESSMENT,
DIAGNOSIS, TREATMENT AND PREVENTION OF NON-SMALL CELL LUNG

Assistant Commissioner for Patents

CANCER

Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
 (When using Express Mail, the Express Mail label number is mandatory;
 Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10*

☐ with sufficient postage as first class mail.☒ as "Express Mail Post Office to Addressee"Mailing Label No. 439671498 (mandatory.)**TRANSMISSION**☐ transmitted by facsimile to the Patent and Trademark Office.Date: 2-25-05

Signature

Janel L. Erdmann
Janel L. Erdmann

(type or print name of person certifying)

(Information Disclosure Statement [6-1]—page 1 of _____)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

(1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

(3) Before the mailing date of a first Office action on the merits; or

(4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) each inventor named in the application;

(2) each attorney or agent who prepares or prosecutes the application; and

(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(d).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement; discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☐ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

(Information Disclosure Statement [6-1]—page 2 of _____)

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/508,932
				Filing Date	September 24, 2004
				First Named Inventor	James. C. Willey et al.
				Group Art Unit	
				Examiner Name	
Sheet		of		Attorney Docket Number	04132

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		JAMES C. WILLEY, ERIN L. CRAWFORD, CLARA M. JACKSON, DAVID A. WEAVER, JEREMY C. HOBAN, SADIK A. KHUDER AND JEFFREY P. DEMUTH-Expression Measurement of Many Genes Simultaneously by Quantitative RT-PCR Using Standardized Mixtures of Competitive Templates-Rapid Communication-Published 1998 - American Journal of Respiratory Cell and Molecular Biology - Vol 19- 12 pages-US	
		JEFFREY P. DEMUTH, CLARA M. JACKSON, DAVID A. WEAVER, ERIN L. CRAWFORD, DENNIS S. DURZINSKY, SAMUEL J. DURHAM, AIMAN ZAHER, EDWIN R. PHILLIPS, SADIK A. KHUDER AND JAMES C. WILLEY - The Gene Expression Index c-myc X E2F-1/p21 Is Highly Predictive of Malignant Phenotype in Human Bronchial Epithelial Cells- Rapid Communication- Published 1998-7 pages-American Journal of Respiratory Cell and Molecular Biology Vol. 19-US	
		JEFFREY K. ACTOR, JOSEF R. LIMOR AND ROBERT L. HUNTER - A Flexible Bioluminescent-Quantitative Polymerase Chain Reaction Assay for Analysis of Competitive PCR Amplicons - Journal of Clinical Laboratory Analysis - Published 1999 - 8 pages - US	
		B. W. S. ROBINSON, D.J. ERLE, D.A. JONES, S. SHAPIRO, W. J. METZGER, S. M. ALBELDA, W.C. PARKS AND A. BOYLAN - Recent advance in molecular biological techniques and their relevance to pulmonary research - Occasional review - Published 2000 - 11 pages - US	
		EP International Search Report- 02-11-2005	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☒ supplied by the inventor(s).
☒ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
☒ in the practitioner's file.



SIGNATURE OF PRACTITIONER

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(Information Disclosure Statement—Section 10. Identification of Person(s) Making This Information Disclosure Statement [8-1]—page ____ of ____)